K091735

12. Summary of Safety and Effectiveness

SEP 25 2009

Submitter

Name of company: S&C Polymer Silicon- und Composite Spezialitaeten GmbH

Address: Robert-Bosch-Strasse 5, D-25335 Elmshorn (Germany)

Phone: 0049 4121 483 0

Fax: 0049 4121 483 184

Contact Person: Dr. Christian Boettcher

Date of preparation: June 2009

Device Name:

Trade name: Provi Cem Esthetic

Common Name: Provi Cem Esthetic (consisting of DC Provi Cem Esthetic, DC Provi Cem Esthetic Multi F and DC Provi Cem Implant)

Classification Name: Cement Dental, per 21CFR § 872.3275

Devices for which Substantial Equivalence is Claimed:

Tempbond Clear, K982590

Device description and Intended Use of the device:

Provi Cem Esthetic consist of three different cements:

DC Provi Cem Esthetic and DC Provi Cem Esthetic Multi F: Intended for cementing temporary restorations such as crowns, bridges, inlays or onlays; as well as for trial cementing of permanent restorations;

DC Provi Cem Implant: Intended for cementing of semi-permanent implants;

All cements can also be used as temporary filling materials

Substantial Equivalence:

Provi Cem Esthetic is substantially equivalent to other legally marketed devices in the United States. The Cements marketed by S&C Polymer Silicon- und Compositen Spezialitaeten GmbH function in a manner similar to and is intended for the same use as the products marketed by Sybron Dental Specialities, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 25 2009

Dr. Christian Boettcher
Official Correspondent
S& C Polymer GmbH
Robert-Bosch –Strasse 5
Elmshorn, Germany D-25335

Re: K091735
Trade/Device Name: Provi Cem Esthetic (DC PROVI Cem Esthetic, DC Provi Cem Esthetic Multi F, and DC Provi Cem Implant)
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: September 11, 2009
Received: September 15, 2009

Dear Dr. Boettcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. Statement of Indication for Use

510(k) Number (if known): -

Device Name: Provi Cem Esthetic
(consisting of three different cements):

Indications for Use:

DC Provi Cem Esthetic and
DC Provi Cem Esthetic Multi F:

Intended for cementing temporary restorations such as crowns, bridges inlays or onlays; as well as for trial cementing of permanent restorations;

DC Provi Cem Implant:

Intended for cementing of semi-permanent implants;

all cements can also be used as temporary filling materials

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

10(k) Number: K091735

Prescription Use: or Over-The-Counter Use